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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/361,425	07/27/99	KUNG	J JBP461

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HM12/0110

EXAMINER
ROBINSON, P

ART UNIT	PAPER NUMBER
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1653

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DATE MAILED: 01/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/361,425

Applicant(s)

KUNG ET AL.

Examiner

Patricia A Robinson

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4, 14 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-13 and 15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 17) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other:

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, drawn to compositions containing oil-soluble and/or water-soluble oxygen-labile species and stabilizer compounds, classified in class 514, subclasses 2-21, 252/149, 531/1, 530/395, 436/8, 514/251, 544/243, 544/296, 514/930 and 424/70.51.
- II. Claim 16, drawn to a method of stabilizing oil-soluble or water-soluble oxygen-labile compositions; classified in class 252, subclass 1.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct sub-genus of the claimed invention: oil-soluble oxygen labile and water-soluble oxygen labile compounds. Each sub-genus is structurally and functionally divergent and would require separate non-overlapping searches.

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In addition, this application contains claims directed to the following patentably distinct species of the claimed invention: retinoids, choleciferol, vitamin K tocotrienol, fatty acids, and tocopherol and their derivatives. Each species is distinct in its chemical structure and can be utilized in divergent manners and thus a separate search would be required for each individual species.

Finally, this application contains claims directed to the following patentably distinct species of the claimed invention: ascorbic acid and its derivatives; niacin; thiamin; riboflavin; folic acid; pyrodoxine; panthothenic acid; niacinamide; lipoic acid; dihydrolipoic acid; amino acids and their derivatives. Due to the distinctness in chemical structure and utility, a search for one compound would not necessarily overlap with another. Thus requiring an individual search be conducted for each species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed sub-genus and a species therefrom for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification and structure for the sub-genus and species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional sub-geni and species which are written in dependent form or

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otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the sub-genus are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sub-genus to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claim 1 is generic to a plurality of disclosed patentably distinct sub-genus comprising thio-containing compound and glycoproteins. Applicant is required under 35 U.S.C. 121 to elect a single disclosed sub-genus, even though this requirement is traversed.

Should applicant traverse on the ground that the sub-genus are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sub-genus to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application also contains claims directed to the following patentably distinct species of the claimed invention: sulfites; metabisulfites; glutathione; and cysteine

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derivatives. Due to the distinctness in chemical structure and utility, a search for one compound would not necessarily overlap with another. Thus requiring an individual search be conducted for each species.

Applicant is required under 35 U.S.C. 121 to elect and provide the structure for a single disclosed sub-genus and species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic. Each sub-genus is structurally and functionally divergent and would require separate non-overlapping searches.

Applicant is advised that a reply to this requirement must include an identification of and the structure of the sub-genus and the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional sub-genus and species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the sub-geni or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that

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this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with William McGowan on 11/18/99 a provisional election was made with traverse to prosecute the invention of 1, claims 1-15. Affirmation of this election must be made by applicant in replying to this Office action. Claim 16 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. In addition, an election with the following components was selected, oil-soluble retinoids with thio-containing n-acetylcysteine as the stabilizer. Claims 1, 2, 5-13 and 15 were examined as they pertain to the elected species and genus selected for examination by Applicant. Claims 3, 4, and 14 were withdrawn from consideration as they are drawn to a non-elected species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1, 2, 5-13, and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for water-in-oil emulsion compositions, does not reasonably provide enablement for compositions where n-acetylcysteine is present as the sole stabilizer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification examples all teach compositions that result in water-in-oil emulsions where n-acetylcysteine is present in combination with lactoferrin or ascorbic acid, each of which acting as a antioxidant stabilizer. The claims, however, teach the ability to make and use a stable composition where n-acetylcysteine is the sole stabilizer in combination with the oil-soluble oxygen labile species retinoids. In addition, the claims embrace compositions that are non-emulsions, while the scope of the teachings in the specification is limited to emulsion type compositions. Thus, the scope of the claims is not sufficiently enabled in the specification, as the disclosure would not teach one skilled in the art to practice the full breadth of invention as identified by the claims. For examination purposes the phrase "containing" was interpreted as "comprising", i.e. as open claim language.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5-13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by REED *et al.* (N).

REED teaches the incorporation of retinoids in water-in-oil emulsions (page 1), and the susceptibility of the retinoid to oxidation in water-in-oil emulsion and hence a short shelf-life of the emulsion compositions (page 1). REED also teaches the use of antioxidants to improve the oxidative stability of retinoid-containing water-in-oil emulsions (page 2). Finally REED teaches the use of n-acetylcysteine in the composition (page 10). Thus REED teaches a water-in-emulsion composition encompassing retinoid and n-acetylcysteine for use in the skin care industry, and therefore claims 1, 2, 5-13, and 15 are anticipated.

Conclusion

Claims 1, 2, 5-13, and 15 are rejected.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. ZHANG *et al.* (A); HOSTETTLER *et al.* (B); MASON *et al.* (C); DeVries and DeFlora (U).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A Robinson whose telephone number is 703-305-0096. The examiner can normally be reached on 7:30 - 4:30 Monday - Friday.